Section 1: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

I. General Information

Device Name	Trade Name:	31P/1H headcoil for MAGNETOM Allegra
	Classification Name:	Magnetic Resonance Diagnostic Device
	CFR Section:	CFR § 892.1000
	Classification:	Class II
	Product Code:	MOS - Magnetic Resonance Specialty Coil

Manufacturer
Bruker BioSpin MRI GmbH
Rudolf-Plank-Straße 23
D-76275 Ettlingen, Germany

Registration Number 9612385

Initial Importer/ Distributor
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Registration Number 2240869

Contact Person
Nealie Hartman
Technical Specialist, Regulatory Affairs
Siemens Medical Solutions
51 Valley Stream Parkway E-50
Malvern, PA 19355
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Performance Standards None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Supporting Substantial Equivalence

Device Description
The 31P/1H headcoil for MAGNETOM Allegra is a transmit/receive birdcage type quadrature headcoil double resonant on phosphorus (31P) and proton (1H) frequencies. It is optimized for the main application: 31P spectroscopy potentially including also proton decoupling.

The coil consists of the resonator and an electronic box, which serves for switching transmit/receive, quadrature splitting, preamplifying and lowpass filtering in the receive pathway. The latter being essential for proton decoupling.

Intended Use
The 31P/1H headcoil for MAGNETOM Allegra is a transmit/receive birdcage type headcoil double resonant on phosphorus (31P) and proton (1H) frequencies.

Used in the Allegra system it is indicated for use as a diagnostic imaging device to produce 1H images and 1H spectra of the internal structures of the head. In addition, 31P spectra can be obtained within the same session without changing the coil.

The images produced reflect the spatial distribution of protons exhibiting magnetic resonance. Spectra allow the molecules, in which the nucleus under investigation is contained, to be distinguished. The NMR properties that determine the image and spectra appearance are spin density, spin-lattice relaxation time (T1), spin-spin echo time (T2) and resonance frequency of the corresponding nucleus.

When interpreted by a trained physician, these images and spectra provide information that can be useful in determining diagnosis.

Substantial Equivalence
Bruker and Siemens believe that, within the meaning of the Safe Medical Device Act of 1990, the 31P/1H headcoil for MAGNETOM Allegra is substantially equivalent to three coils:

Coil Name	Premarket Notification	Clearance Date
Siemens Medical Solutions 31P/1H heart/liver coil for Clinical Phosphorus Spectroscopy Option MAGNETOM Vision	K962627	March 04, 1997
Siemens Medical Solutions 31P/1H heart/liver coil included in *syngo* MR 2002B	K020991	June 13, 2002
GE Medical Systems Signa 1.5T Phosphorus Transmit/Receive Flex Coil	K983139	February 19, 1999

Besides 1H imaging, these coils allow the non-invasive in vivo analysis of 31P-metabolites such as phosphocreatine (PCr), inorganic phosphate (Pi) or adenosine triphosphate (ATP) relevant in energy metabolism. The regions applied are heart, liver, muscle, and head.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2004

Ms. Nealie Hartman
Technical Specialist, Regulatory
Affairs Submissions
Siemens Medical Solutions, Inc., USA
51 Valley Stream Parkway
MALVERN PA 19355

Re: K042617
Trade/Device Name: 31P/1H headcoil for
MAGNETOM Allegra System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance
diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: September 23, 2004
Received: September 24, 2004

Dear Ms. Hartman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K042617

Device Name: 31P/1H headcoil for MAGNETOM Allegra System

Indications for Use:

The 31P/1H headcoil for MAGNETOM Allegra is a transmit/receive birdcage type headcoil double resonant on phosphorus (31P) and proton (1H) frequencies.

Used in the Allegra system it is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique 1H images and 1H spectra of the internal structures of the head. In addition, 31P spectra can be obtained within the same session without changing the coil.

The images produced reflect the spatial distribution of protons exhibiting magnetic resonance. Spectra allow the molecules, in which the nucleus under investigation is contained, to be distinguished. The NMR properties that determine the image and spectra appearance are spin density, spin-lattice relaxation time (T1), spin-spin echo time (T2) of the corresponding nucleus.

When interpreted by a trained physician, these images and spectra provide information that can be useful in determining diagnosis.

(please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use ____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042617